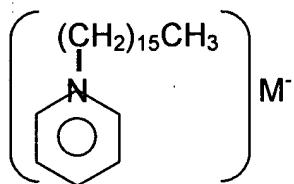


## REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Upon entry of the amendments this application will contain claims 1-22 pending and under consideration. Of these, claim 5 has been formally amended to correct an antecedent basis issue, and claim 22 is new. The remainder of the claims remain unchanged. It is believed that this Amendment and Reply addresses and overcomes all outstanding rejections. Accordingly, allowance is solicited.

Claims 1-21 stand rejected under 35 USC § 103(a) as being unpatentable over Spanier et al. (US Patents 5011679 and 5114704) in view of Witt et al. (US Patent 6350438) or Glandorf et al. (US Patent 6521216) and further in view of Perlberg et al. (US Patent 6223693). For the reasons detailed below, it is submitted that this rejection is overcome with regard to claims 1-21, and is also inapplicable to new claim 22. Accordingly, withdrawal of this rejection is solicited.

Claims 1-15 of the application are directed to animal chew products, articles, or methods, that include or involve "an ingestible chew substrate" and "a cetyl pyridinium salt and sodium tripolyphosphate incorporated on or in said ingestible chew substrate". Claims 16-21 of the application are direct to methods for manufacturing animal chew products that include "providing an ingestible chew substrate" and "incorporating sodium tripolyphosphate and a cetyl pyridinium salt on or in said substrate". Cetyl pyridinium salts such as cetyl pyridinium chloride have the formula:



Sodium tripolyphosphate has the formula  $\text{Na}_5(\text{P}_3\text{O}_{10})$ . As directly demonstrated in the in vitro zone of inhibition testing set forth in Example 1 beginning at page 10 of the application, the Applicant has discovered that cetyl pyridinium chloride

is compatible with sodium tripolyphosphate when mixed, and that bacterial organisms such as those believed to be involved in oral health issues are significantly inhibited by this mixture. As demonstrated directly in the clinical dog study set forth in Example 2 beginning at page 12 of the application, rawhide chew products incorporating the combination of sodium tripolyphosphate and cetyl pyridinium chloride provide improved oral health including reductions in gingivitis, dental plaque, and dental calculus (see Table 2, page 14, and comments thereon). Furthermore, the chew products incorporating the combination of sodium tripolyphosphate and cetyl pyridinium chloride provided an unexpected reduction in mouth odor in the dogs, as reported at page 14 of the application.

Turning now to the legal framework provided for under 35 USC 103(a), When rejecting claims under this statute, “the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art.” *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, the Examiner must provide objective evidence 1) of some suggestion or motivation to combine or modify one or more prior art references, 2) that the suggested combination or modification has a reasonable expectation of success, and 3) that the prior art reference or references, when combined, suggest or teach all of applicant’s claim limitations. MPEP § 2143. As held by the Federal Circuit, “[t]hese findings or evidence must be specific, clear, and particular.” *In re Lee*, 61 U.S.P.Q. 2d 1430, 1433-34 (Fed. Cir. 2002). “Broad conclusory statements regarding the teaching of multiple references, standing alone, are not [considered sufficient] ‘evidence’ ” to support a finding of *prima facie* obviousness. *In re Dembicza*k, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999); See also, *Ex Parte Levengood*, 28 U.S.P.Q. 2d 1300, 1301 (Bd. Pat. App. & Int. 1993). Moreover, citing references which merely indicate that isolated elements recited in the claims are known is not a sufficient basis for concluding that the combination of claimed elements would have been obvious. *Ex parte Hiyamizu*, 10 U.S.P.Q. 2d 1393 (BPAI 1988).

Obviousness determinations must be performed without “entry into the ‘tempting but forbidden zone of hindsight.’” *Dembiczak*, 50 U.S.P.Q. 2d at 1616 (Fed. Cir. 1999). More specifically, in *Dembiczak*, the Federal Circuit offered the following guidance:

[m]easuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. . . .

*Dembiczak*, 50 U.S.P.A. 2d at 1617. The best protection against the use of hindsight is a rigorous application of the motivation criterion, which results in most *prima facie* obviousness determinations hinging on an objective finding of some motivation or suggestion to combine or modify one or more prior art references. See, *Dembiczak*, 50 U.S.P.Q. 2d at 1617; *In re Roufett*, 47 U.S.P.Q. 2d 1453, 1457-58 (Fed. Cir. 1998).

Similarly, “obvious to try” is not a valid test of patentability. *In re Dow Chemical Co.*, 5 U.S.P.Q. 2d (CAFC 1988). Relevant to the present case, the prior art must provide a reasonable expectation of success that a trial of the claimed combination would be successful [*In re Pantzer et al.*, 144 U.S.P.Q. 415 (CCPA 1965); *In re Longi et al.*, 225 U.S.P.Q. 645 (CAFC 1985)] and low levels of predictability exist in arts involving chemical reactions and physiological activity. *In re: Fisher*, 166 U.S.P.Q. 18 (CCPA 1970); *In re Hogan et al.*, 194 U.S.P.Q. 527 (CCPA 1977).

With this background, it is submitted that the combination of references and remarks in the Office Action fails to establish a *prima facie* showing that the claims presently pending are obvious. In particular, the rejection that is stated in the Office Action relies upon the Spanier et al. references as primary references, and then suggests that certain features from the other references (Witt et al. or Glandorf et al, further in view of Perlberg et al.) could be incorporated into the

Spanier et al. references to arrive at the present claims. Specifically, to support the rejection, the remarks made in the Office Action state that:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply or incorporate in rawhide, with a composition such as that of Spanier et al. for its benefit as an anti-calculus agent and to combine such a composition with cetyl pyridinium salt, for its established benefit as an antimicrobial agent.

In response, the Applicant would like to first point out that even if the substitution proposed in the excerpt above was made, one would not have the elements of the present claims. The Spanier et al. references teach the use of certain pyrophosphate compounds as anti-calculus agents, that is, compounds that deliver an amount of the  $P_2O_7$  anion to the subject animal. In this regard, the Spanier et al. references expressly state that:

The pyrophosphate(s) is used in sufficient amount to delivery generally form about 0.1 to about 5, preferably from 0.4 to 0.5 weight percent (based on the total composition) of  $P_2O_7$ .

Col. 12, lines 41-44. This is consistent with the definition of pyrophosphates given at Col. 12, lines 3-7, wherein n is 2 in the formula  $M_{n+2}P_nO_{3n+1}$ . On the other hand, sodium tripolyphosphate, as is presently claimed, would not be expected to deliver the  $P_2O_7$  anion to the subject animal. Rather, sodium tripolyphosphate,  $Na_5(P_3O_{10})$ , would be expected to deliver the  $P_3O_{10}$  anion to the subject animal. Thus, as can be seen, even following the statements set forth in the Office Action by adding cetyl pyridinium chloride to the compositions described by Spanier et al. would not result in a composition having the elements of the present claims. Because the rejection made must establish motivation to arrive at all claimed elements (see MPEP § 2143) in a fashion that is “specific, clear, and particular” [*In re Lee*, 61 U.S.P.Q. 2d 1430, 1433-34 (Fed. Cir.

20020)], it is submitted that the stated rejection does not provide a *prima facie* case of obviousness and should be withdrawn.

Moreover, the present case involves both chemical reactivity and physiologic response variables, recognized high contributors to unpredictability. See, *In re: Fisher and In re Hogan et al., supra*. Through actual testing and clinical trials the Applicant has discovered that the combination of sodium tripolyphosphate and cetyl pyridinium chloride is compatible and active (Example 1) and their incorporation and use in a dog chew product leads to significant improvements in oral health including reducing the incidence of gingivitis, dental plaque and dental calculus (Example 2). Still further, the chew product with the combination of sodium tripolyphosphate and cetyl pyridinium chloride led to a significant reduction in mouth odor (Example 2). It is submitted that the prior art relied upon in the Office Action and the remarks do not establish the necessary expectation of success for a rejection for obviousness [see *In re Pantzer et al.* and *In re Longi et al., supra*] and that the rejection as maintained would amount to one made based upon an improper "obvious to try" standard (see *In re Dow Chemical Co, supra*) using hindsight analysis (see *In re Dembiczak, supra*).

For the foregoing reasons, it is submitted that the rejection of claims 1-21 under 35 USC § 103(a) is improper and should not be maintained.

Reconsideration and withdrawal of this rejection are thus solicited.

The Examiner will note that new claim 22 has been added to the application. This claim finds support, for example, in the last paragraph of page 8 ("substantially homogenous") and in the first paragraph of page 9 (rawhide particles and size). It is believed that this claim is allowable for the above reasons at the least.

In view of the foregoing, allowance of this application containing claims 1-22 is requested. The Examiner is invited to contact the undersigned attorney by telephone if there are any questions about this submission or if there are other matters that may be handled in that fashion to expedite the allowance of this application.

Respectfully submitted,

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